IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF MISSOURI
WESTERN DIVISION

UNITED STATES OF AMERICA ex rel. LONNIE PAULOS, MD,	)	
Relator/Plaintiff,	)	
v.	)	Civil No. 11-0041-CV-W-ODS
STRYKER CORPORATION, et al.,	)	
Defendants.	)	

ORDER AND OPINION GRANTING DEFENDANTS' MOTION TO DISMISS

Doctor Lonnie Paulos (hereinafter "Plaintiff") brings this qui tam action pursuant to 31 U.S.C. § 3730, alleging Defendants violated the False Claims Act ("FCA"), 31 U.S.C. § 3729. Section 3730 establishes circumstances under which a private individual – who is often referred to as the "relator" because they bring suit on behalf of the Government – may file a civil action against a party who is alleged to have violated the FCA by submitting a false or fraudulent claim for payment to the Government. The three remaining defendants have filed a Motion to Dismiss (Doc. # 54), which is granted.

I. BACKGROUND

Plaintiff initiated this suit in January 2011. After numerous extensions, in December 2012 the Government indicated it was not exercising its right to intervene and the Complaint was unsealed and formally served on three Defendants: Stryker Corporation, I-Flow Corporation, and Orthofix International. Orthofix is sued solely in its capacity as the successor in interest to Breg, Inc., and Plaintiff's allegations describe only actions taken by Breg. The fourth defendant, DJO Incorporated, was dismissed on May 9, 2013, because Plaintiff did not effectuate service. The three served Defendants filed Answers; they also filed a Motion to Dismiss that was supported by jointly submitted suggestions in support and separate individual suggestions.

The motion is now fully briefed. In the midst of the briefing process, Plaintiff was granted leave to file an Amended Complaint that (1) formalized DJO's dismissal by removing it as a defendant and (2) added additional information about the use of the pain pumps at issue in this case. The Court has previously indicated the Amended Complaint did not obviate the issues raised in Defendants' motion, and the Court and the parties have proceeded with the understanding that the Amended Complaint did not moot the issues raised in the motion. Nonetheless, Defendants filed an additional motion to dismiss that was unaccompanied by any additional suggestions to support it. The Court interprets this motion to be duplicative of the original motion and grants it (Doc. # 101) just so the Record is complete.

Plaintiff's suit addresses the marketing of pain pumps, which are medical devices that inject an anesthetic into the body through a catheter. The Food and Drug Administration ("FDA") approved use of the pain pumps in certain areas of the body but had not approved them for use in connection with orthopedic surgeries generally or – more importantly – for use in the space within joints such as the shoulder. Defendants allegedly marketed their pain pumps for use in joint space[1] even though the FDA declined approval for such use. The pumps were actually used for these unapproved purposes, and doctors and hospitals then sought reimbursement from various federally administered or created programs, such as Medicare, Medicaid, and the Veterans' Administration. Plaintiff contends reimbursement is not allowed for medical devices that are used for purposes not approved by the FDA, so all claims for payment were false and Defendants violated the FCA by causing these false or fraudulent claims for payment to be made. This theory forms the focus of the second and third "subclaims" of Counts I – IV. Amended Complaint, ¶¶ 197(b) & (c), 204(b) & (c), 211(b) & (c), 218(b) & (c).[2]

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[1]The parties use the terms "intra-articular space," "synovial cavity," and "joint space" interchangeably to refer to the space surrounding a joint. The Court will follow suit.

[2]In response to the Motion to Dismiss Plaintiff insists that "the use of pain pumps in orthopedic surgery was not an 'off label' use'" because the pain pumps were explicitly marketed for such use. Plaintiff's Suggestions in Opposition (Doc. # 74) at 2-3. This seems to contradict the explicit allegations of the Amended Complaint; for instance,

The Amended Complaint also claims deleterious health effects arise from the use of pain pumps in joint space. Specifically, the use of pain pumps in joint space is alleged to result in chondrolysis, which involves damage to cartilage in the joint. In addition to repeated allegations about the injuries suffered by patients, Plaintiff avers that Defendants failed to (1) disclose these facts to doctors and hospitals and (2) make required reports of these adverse effects to the FDA. The former allegation is presented as the first subclaim for Counts I – IV, which allege Defendants induced doctors and hospitals to submit false claims for payment in violation of 31 U.S.C. § 3729(a)(1)(A). Amended Complaint, ¶¶ 197(a), 204(a), 211(a), 218(a).[3] The latter assertion is presented to support Count VI, which claims Defendants "made and used false records" whey they "fail[ed] to issue Medical Device Reports [to the FDA] on the failures of the Pain Pumps in use inside the synovial cavity," which allegedly violates 31 U.S.C. § 3729(a)(1)(B). Amended Complaint, ¶ 239.[4]

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paragraph 17 alleges the "fraud alleged in this complaint arises out of false claims . . . related to the off-label marketing of pain pumps for use inside joints when such use had been specifically denied by" the FDA. Ultimately, the Court is not sure that it matters whether the phrase "off label" properly applies to these circumstances.

[3]As an aside: the Court harbors doubts about this subclaim's viability to the extent it is predicated on the theory that Defendants' actions were "fraudulent" simply because they will cause future health care costs to be absorbed by the Government. If this theory were viable, then *every* failing by a drug or device manufacturer would give rise to an FCA claim. However, this is not the only basis for the subclaim, (and the claims are being dismissed for other reasons), so there is no need to delve into this issue further.

[4]Count VI actually cites section 3729(a)(1)(A), but given Count VI's assertion regarding false records the Court agrees with Defendants that this is probably a typographical error and the proper statutory reference is section 3729(a)(1)(B). See also Plaintiff's Suggestions in Opposition at 24.

II. DISCUSSION

A. The False Claims Act's Public Disclosure Bar

1.

At one time the FCA contained no limitation on the source of the relator's knowledge. In 1946 Congress added, and over time has modified, a bar precluding suit if the relator's knowledge came from various sources in order to balance the desire to encourage whistleblowing against a need to prevent claims from "opportunistic" or "parasitic" plaintiffs who provided no real information to the Government. See Graham County Soild & Water Conservation Distr. v. United States ex rel. Wilson, 130 S. Ct. 1396, 1406-07 (2010); Costner v. URS Consultants, Inc., 153 F.3d 667, 675-76 (8th Cir. 1998). This provision of the FCA is often referred to as the Public Disclosure Bar and is codified at 31 U.S.C. § 3730(e)(4).

The events in this case straddle two versions of the Public Disclosure Bar, in that (1) the wrongdoing allegedly began in 2004[5] and (2) Congress amended the Public Disclosure Bar in 2010 when it passed the Patient Protection and Affordable Care Act ("PPACA"). The parties disagree as to the legal effect of this evolution. Plaintiff argues the 2010 version applies because he filed suit in January 2011. Defendants argue that both versions apply: the current version applies to conduct occurring after the PPACA was passed, and the prior version applies to conduct occurring before the PPACA was passed. The Court concludes (1) if it matters, Defendants are correct and (2) under the circumstances of this case it does not matter.

The guiding authority is the Supreme Court's decision in *Hughes Aircraft Co. v. United States ex rel. Schumer*, 520 U.S. 939 (1997). In that case, Hughes Aircraft allegedly submitted false claims between 1982 and 1984. The relator filed suit in January 1989, and there was no dispute that at that time the Government was aware of

[5]This date may or may not be accurate because Plaintiff has not clearly indicated when any Defendant began marketing pain pumps to doctors and hospitals for use in joint space or when any FCA violations first occurred. Regardless, it is clear that the date is before 2010.

the underlying information, but the underlying information had not been publicly disclosed. 520 U.S. at 945. Before 1986, the Public Disclosure Bar prohibited qui tam actions when the Government already had the information, even if that information was not publicly disclosed. However, in 1986 – between submission of the last false claim and the filing of the suit – Congress limited the bar's applicability by amending section 3730(b)(4) "to permit *qui tam* suits based on information in the Government's possession, except where the suit was based on information that had been publicly disclosed and was not brought by an original source of the information." Id. at 946. The relator contended the applicable version of section 3730(e)(4) was the one that existed when the suit was filed, making the suit permissible because while the Government knew the information it had not been publicly disclosed before the suit commenced. The Supreme Court disagreed. Id. In so doing, the Court treated the issue as one involving retroactivity; namely, whether the amended version of section 3730(e)(4) should apply to conduct that occurred before the amendment was passed. Noting a "deeply rooted" presumption against retroactivity, and finding no clear intent by Congress to overcome the presumption, the Court held the applicable version of section 3730(e)(4) was the one that existed when the conduct complained of occurred. Id. at 946-52. The Court did not decide whether the event constituting "relevant conduct" for retroactivity purposes was submission of the false claim or the Government's discovery of information about the false claim because both events occurred before the amendment. Id. at 946 n.4. However, the Supreme Court's unanimous decision makes one thing clear: the date of filing does not dictate which version of section 3730(e)(4) applies.

2.

Construing Plaintiff's allegations broadly, the "old" Public Disclosure Bar applies to some of Defendants' conduct and the later version applies to other conduct. Plaintiff has not specified when the allegedly false claims were submitted, but it is clear that most if not all were submitted before the PPACA was passed. Thus, with respect to most (if not all) claims the pre-PPACA version of section 3730(e)(4) applies. Because

some of the allegedly false claims may have been submitted after the PPACA was passed the Court must also consider the current version of section 3730(e)(4). As foreshadowed, in the circumstances of this case the differences do not matter.

Pre-PPACA, the Public Disclosure Bar dictated that a district court lacked jurisdiction over any qui tam action based upon conduct that was publicly disclosed "in a criminal, civil or administrative hearing, in a congressional, administrative, or Government Accounting Office report, hearing, audit, or investigation, or from the news media" unless the relator was "an original source of the information." The statute further defined an "original source" as an individual possessing "direct and independent knowledge of the information on which the allegations are based" and who "voluntarily provided the information to the Government before filing" the qui tam suit.

After the 2010 amendment, the bar does is not described as jurisdictional in nature; instead, the statute simply directs that the action or claim be dismissed "if substantially the same allegations or transactions as alleged in the action or claim were publicly disclosed." The circumstances under which a hearing could constitute public disclosure were also narrowed; now, the disclosure must occur in a *federal* criminal, civil, or administrative hearing in which the Government is a party. The categories of reports constituting public disclosure were expanded to encompass congressional, GAO, or any other "Federal report, hearing, audit, or investigation." The reference to disclosure through the media remained unchanged.[6] The definition of "original source" was amended, and now encompasses any individual who (1) discloses the information to the Government before it is publicly disclosed or (2) "has knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions" and provides the information to the Government before filing the qui tam action.

In contending the differences are important, Plaintiff focuses on the fact that the pre-2010 version imposed a jurisdictional bar while the amended version allows only for dismissal. A challenge to a federal court's jurisdiction is governed by Rule 12(b)(1), and

[6]The 2010 amendment also added a clause indicating the Public Disclosure Bar should apply "unless opposed by the Government." The Government has not opposed application of the Public Disclosure Bar. In this regard the Court notes the Government's filing the Court ordered to be struck, see Order dated May 28, 2013, did not oppose dismissal based on (or even mention) the Public Disclosure Bar.

materials outside the pleadings may be considered. E.g., Harris v. P.A.M. Transport, Inc., 339 F.3d 635, 637 & n.4 (8th Cir. 2003); see also Fed. R. Civ. P. 12(d) (requirement to convert Rule 12 motion to motion for summary judgment applies only to motions filed under Rule 12(b)(6) and 12(c)). Assuming section 3730(e)(4)'s directive that the Public Disclosure Bar requires "dismissal" means dismissal under Rule 12(b)(6) (an issue that is neither clear nor addressed by the parties), Plaintiff overstates the rigidity of the rule prohibiting consideration of materials outside the pleadings. For instance, the Court may consider (1) exhibits attached to the Complaint and (2) materials necessarily embraced by the Complaint even if they are not attached to the Complaint. Mattes v. ABC Plastics, Inc., 323 F.3d 695, 698 (8th Cir. 2003). The Court may also consider facts of which it may take judicial notice. E.g., Dittmer Properties, L.P. v. Federal Deposit Ins. Corp., 708 F.3d 1011, 1021 (8th Cir. 2013) (citing Miller v. Redwood Toxicology Laboratory, Inc., 688 F.3d 928, 931 & n.3 (8th Cir. 2012)). This latter point is critical in the present case, because all of the material Defendants have submitted consists of documents filed in court proceedings, media reports, and reports from government agencies. The Court can take judicial notice of the contents of these materials in order to ascertain whether they disclosed the allegations upon which this lawsuit is based. Thus, the Court can consider the exhibits submitted by Defendants regardless of which version of section 3730(e)(4) applies.

Plaintiff has submitted a Declaration along with his Suggestions in Opposition to Defendants' motion. In a reversal of roles, Defendants encourage the Court to ignore the Declaration because it includes allegations not included in the Amended Complaint. As explained earlier, to the extent Defendants' argument is predicated on the jurisdictional attack provided by the pre-PPACA version of the Public Disclosure Bar, Rule 12(b)(1) permits the Court to consider materials outside the pleadings. Granted, an undetermined portion of Plaintiff's claims arose after the Public Disclosure Bar was amended, and post-amendment it may be that Rule 12(b)(6) applies. Nonetheless, the Court will consider Plaintiff's Declaration because it ultimately does not help him.

2.

Having taken this long walk to the door, the Court can finally enter and discuss the Public Disclosure Bar's application to this case. The two versions employ different language but the analysis is essentially the same. The Court thus concludes that pre-PPACA cases remain instructive and the following issues must be considered:

1. Have Plaintiff's allegations been "publicly disclosed," as described in section 3730(e)(4)?
2. Is the suit based on the public disclosure?
3. If the answer to these questions is "yes," was Plaintiff the "original source" of the information as that phrase is defined in section 3730(e)(4)?

E.g., United States ex rel. Kinney v. Stoltz, 327 F.3d 671, 674 (8th Cir. 2003); Minnesota Ass'n of Nurse Anesthetists v. Allina Health Sys. Corp., 276 F.3d 1032, 1042 (8th Cir.), cert. denied, 537 U.S. 944 (2002). With respect to the second component, the Eighth Circuit has adopted the majority rule dictating that "a qui tam suit is 'based upon' a public disclosure whenever the allegations in the suit and in the disclosure are the same, regardless of where the relator obtained his information." Id. at 1045 (quotations and citations omitted). Thus, demonstrating the suit is "based on" the public disclosure does not require finding that Plaintiff obtained his information from the public disclosure; it only requires proof that the suit is based on facts that have already been publicly disclosed as defined in the statute. Id. at 1047.

The first two steps require a comparison of the suit's allegations and facts that were previously disclosed publicly. Counts I through IV assert Defendants

a) Failed to disclose the potential for damage to cartilage from using pain pumps in joint space.
b) Falsely claimed the pain pumps were approved for use inside joints.
c) Falsely labeled or promoted the pain pumps to induce doctors to use the devices.

The Court discerns little difference between the (b) and (c) subclaims, so those subclaims will frequently be addressed together.

Count VI alleges Defendants used false records by failing to make records – specifically, the reports to the FDA about incidents where a patient with a pain pump

experienced chondrolysis. Amended Complaint, ¶¶ 239-41. This failure to file reports with the FDA allegedly caused doctors and hospitals to seek repayment. Amended Complaint, ¶ 244.

According to his Declaration, Plaintiff talked to Government officials in 2010 (no month is specified), although paragraph 10 of the Amended Complaint indicates he did not provide the Government with any information until January 2011. For the sake of argument, the Court will accept 2010 as the year of Plaintiff's first contact with the Government. By that time, all of the allegations asserted in Counts I through IV and Count VI were publicly disclosed.

First, numerous media reports prove this point; a few of them are detailed below with the identifiers employed by Defendants in their exhibits. The Court's failure to list an exhibit should not be construed as a rejection of the value of that exhibit, but rather as an attempt to curtail the length of this Order:

E-1 A July 2006 article on a website devoted to medical issues observed the popular theory that "the cause of chondrolysis is . . . the use of postoperative intra-articular pain pump catheters." The article then cites the results of a study performed by Doctors Hansen, Beck and Townsley, that was part of a presentation to the American Academy of Orthopaedic Surgeons in March 2006.

E-2 An October 2007 article on a website devoted to legal issues refers to Dr. Beck and his warning that "shoulder pain pumps have the potential to cause permanent damage to the shoulder" as well as a study Dr. Beck co-authored that was published in the October 2007 issue of The American Journal of Sports Medicine. Whether this is the same study referenced in E-1 is not clear. The article also mentions the existence of lawsuits alleging the manufacturers "did not warn the medical community that the safety of the pumps had not been fully established [and] did not warn that continuous supply of pain relief medication could cause permanent injury."[7] Interestingly, E-2 also

[7]Media coverage of lawsuits is considered "media coverage" under the Public Disclosure Bar, so the post-PPACA limitation on lawsuits would not apply to a media report about, for instance, a lawsuit (1) to which the Government was not a party (2) that was filed after the PPACA was passed. Cf. United States ex rel. Poteet v. Bahler Medical, Inc., 619 F.3d 104, 110 (1st Cir. 2010) (treating New York Times article about two lawsuits as "disclosures made in the news media"); see also United States ex rel. Fry v. Health Alliance of Greater Cincinnati, 2009 WL 1324164 (S.D. Ohio 2009)

references Defendant I-Flow's public warning to avoid using pain pumps in join space given the "possible association between continuous intra-articular infusions . . . and the subsequent development of chondrolysis."

E-3 A July 2008 article from the Baltimore Daily Record discussing the existence of multiple lawsuits arising from the use of pain pumps in joint space and forthcoming proceedings before the Judicial Panel on Multidistrict Litigation regarding possible consolidation of all such suits in a single district court. Attorneys are quoted as stating the manufacturers "advised doctors to use the devices directly in the shoulder joint, or intra-articularly, a practice not approved by the" FDA.

E-4 An article by Dr. Morrell dated December 2008 appearing in AAOS Now, a website or publication of the American Academy of Orthopaedic Surgeons, entitled "Use of Intra-articular Continuous Infusion Pumps and Chondrotoxicity." The article surveys medical literature establishing a connection between pain pumps and cartilage damage and indicates such literature existed as early as 2004. Several studies are mentioned in a footnote; the earliest such study appeared in the March 2004 edition of the American Journal of Sports Medicine. Dr. Morrell's article also mentions that there were "more than 30 different shoulder pain pump lawsuits" alleging the manufacturers "encouraged doctors to use the devices to directly infuse local anesthetics into the shoulder joint" after "the FDA turned down requests by the device makers to include language in the labeling and promotional materials [stating] direct delivery of local anesthetics into the shoulder joint was, in fact, an approved use of the device."

E-5 A January 2009 article from PR Newswire documenting the filing of six lawsuits seeking recovery for injuries caused by "pain pump[s] delivering local anesthetics into the shoulder joint." The article notes the lawsuits "allege device manufacturers failed to warn the medical community that use of the pain pump directly in the shoulder joint could permanently damage the shoulder" and that some manufacturers sought FDA "approval to use the pumps in the shoulder joint, but failed to disclose to doctors that the FDA denied clearance to market the device for this use on numerous occasions."

(considering whether aspects of litigation were independently reported in media). In any event, the lawsuits referenced in these media reports predate the PPACA's amendment.

E-13 An article from the Wall Street Journal in November 2009 reporting the FDA had received "35 reports of severe cartilage damage in patients who were given pain pumps after surgery" and that "reports about decaying cartilage after shoulder surgery began surfacing several years [before the article] followed by studies in medical journals on orthopedic surgery and sports medicine." The article also describes the FDA's announcement as stating "the FDA did not clear pain pump infusion devices using the anesthetics for 'intra-articular' or joint surgery.

In addition to the media reports, several lawsuits constitute public disclosure. With respect to lawsuits, the Court acknowledges Plaintiff's contention that post-PPACA the only lawsuits that can constitute public disclosure under the statute are suits "in which the Government or its agent is a party." 31 U.S.C. § 3730(e)(4)(A)(i). This limitation did not apply before the PPACA was passed, and as noted the pre-PPACA version of section 3730(e)(4) applies to the extent Plaintiff's claims involve conduct occurring before the PPACA was passed. The Court will further limit its discussion by noting the cases it discusses below predate the PPACA's passage.[8] A representative sampling of relevant complaints involving Defendants follows:

C-1 A suit removed to the Southern District of Indiana in May 2008 alleged I-Flow "disregarded directives of the FDA and marketed these devices in a way that was inconsistent with the health and safety of post-surgical patients" and "fail[ed] to obtain authority by the FDA to market their . . . pain pumps and the anesthetics used therein for use in the intra-articular space, specifically following shoulder surgery." The suit also alleges the defendants failed to adequately test the pain pumps, falsely represented they were safe for use in this manner, and failed to provide adequate or accurate warnings.

[8]The Court doubts information that is publicly disclosed reverts to "undisclosed" status after passage of the PPACA. In other words, if a fact was publicly disclosed in a lawsuit that did not involve the Government before the PPACA was passed, logic dictates that fact remains publicly disclosed after the PPACA was passed. Given the purpose of the Public Disclosure Bar, it makes no sense to construe the PPACA as trying to put the proverbial genie back in the bottle and thereby pretend a fact that was "publicly disclosed" suddenly was not publicly disclosed any longer.

C-2 A June 2008 suit filed in the District of Arizona alleged I-Flow negligently promoted “the pain pumps for use in the joint space after the FDA had considered and rejected such an indication.”

C-3 An October 2008 filed in the Eastern District of Tennessee against I-Flow and Stryker alleged their product labels “failed to disclose to the U.S. medical community that continuous injection of commonly used anesthetics . . . into the shoulder joint space, had not been adequately tested for administration into the joint space and may cause serious and permanent injury to the joint cartilage.” The suit also alleged the defendants “failed to disclose to the U.S. medical community that the FDA” had rejected requests to approve the use of pain pumps “to deliver the pain medication directly into the joint space.”

C-5 A June 2009 suit filed in the District of Colorado alleged Breg promoted “pain pumps for use in the joint space after the FDA had considered and rejected such an indication” and employed labeling that “failed to disclose to the U.S. medical community that the FDA had considered pain pump manufacturers’ requests to include insertion of the pain pump catheter directly into [joint space] . . . and then rejected this precise indication on multiple occasions.”

C-7 A December 2009 suit filed in the Western District of Louisiana against I-Flow, Breg, and Stryker. The suit contains numerous allegations that the defendants marketed and promoted the pain pumps for use in joint space despite knowledge the FDA specifically rejected requests to approve such use. The suit also alleges the defendants “failed to properly investigate and report to the FDA once [they] began receiving reports of dozens of patients who had allegedly suffered injury to their cartilage following use of pain pumps in their shoulder joints.”

Defendants themselves have made numerous public statements reflecting discussions in the medical community about the connection between use of pain pumps in joint space following shoulder surgery and chondrolysis, including:

F-1 I-Flow’s Form 10-Q for the quarter ending June 30, 2007, disclosing “discussion in the orthopedic community over the possibility that the infusion of a local anesthetic into the joint space via a pain pump may contribute to . . . chondrolysis.”).

F-2 I-Flow's Form 10K for the period ending December 31, 2007 (containing a similar disclosure).

G-1 I-Flow's February 2006 Adverse Event Report to the FDA regarding a patient's development of difficulties (including chondrolysis) following use of a pain pump after shoulder surgery.

G-2 A report similar to G-1 involving a different patient.

G-3 A report similar to G-1 involving a different patient.

G-4 A similar report submitted by Breg in April 2008.

G-5 A similar report submitted by Breg in May 2008

G-6 A similar report submitted by Stryker in August 2008

G-7 A similar report submitted by Stryker in October 2008

Finally, the Court notes the existence of several published FDA reports warning the medical community of the connection between the use of pain pumps in joint space and chondrolysis. The earliest such reports (H-1 and H-2) are from November 2009 – unquestionably before Plaintiff's first meeting with federal officials. Six others (H-3 through H-8) are from February 2010. While these could have been published after Plaintiff met with Government officials, the Court mentions them nonetheless because Plaintiff's Declaration curiously fails to be more specific than alleging his initial meeting occurred in 2010. Defendants' exhibits were filed before Plaintiff provided the Court with his Declaration – thus, Plaintiff could have established that his meeting occurred before the six February 2010 FDA reports were issued, but he did not do so. This leads to the suspicion – if not the outright conclusion – that Plaintiff did not provide a narrower timeframe because he did not meet with the Government before the FDA promulgated Exhibits H-3 through H-8. In any event, Exhibits H-1 and H-2 amply demonstrate the FDA publicized the issue before Plaintiff met with the Government in 2010 (again, assuming that is when his meeting occurred).

As noted, Plaintiff's Declaration indicates that he met with federal prosecutors and other representatives from the Department of Justice, the Department of Health and Human Services, and the FDA in 2010 and the Amended Complaint places that meeting in the following year. At that meeting, Plaintiff provided officials with information about the connection between pain pumps and chondrolysis, and the prospect that the federal

government might incur significant future costs associated with joint replacements and other medical treatment as a result of chondrolysis induced by pain pumps. Plaintiff's Declaration, ¶¶ 23-24. He also told these officials that he was concerned about the safety of the pain pumps as early as 2000 (when he became a consultant to Stryker) and began suspecting a connection between the pain pumps and chondrolysis as early as 2002 or 2003, but Defendants generally (and Stryker in particular) did not respond to his concerns. Finally, Plaintiff's Declaration avers that he has "independent and direct knowledge" that some patients who had pain pumps used in joint space "were Medicare, Medicaid or other federal insurance programs patients. Some number of pain pumps were implanted into these patients and the procedures were submitted for payment to the Federal government. There is no doubt that this same process occurred at many other hospitals and surgical centers around the country." Plaintiff also claims to be "certain" that if Defendants disclosed that the FDA rejected requests to approve pain pumps for this use "responsible orthopedic surgeons would not have used them and hospitals would not have submitted such claims for payment to the Federal government." Plaintiff's Declaration, ¶ 12.

Review of these materials reveals the following conclusions:

1. The potential for damage to cartilage from using pain pumps – the (a) allegations in Counts I –IV – was publicly disclosed in numerous media reports, lawsuits, FDA reports, and other public materials before Plaintiff met with Government officials.
2. Allegations that Defendants falsely claimed the pain pumps were approved for use in joints – the (b) and (c) allegations in Counts I – IV – were publicly disclosed in numerous media reports and lawsuits before Plaintiff met with Government officials.
3. The 2009 lawsuit in the Western District of Louisiana (Defendant's Exhibit C-7) disclosed allegations about Defendants' failure to report pain pump complications to the FDA.

Thus, Counts I – IV and VI must be dismissed unless Plaintiff is deemed to be the original source of such information.

Before considering whether Plaintiff was the original source of the information, the Court addresses Plaintiff's contention that there were no public disclosures that doctors and hospitals submitted claims for payment. The question is whether this additional "fact" is sufficiently distinct from the publicly disclosed information such that it qualifies as an independent piece of information. The Court holds that it is not. As cautioned by the First Circuit, courts must be wary of qui tam suits that "add some color" to previously publicized allegations but that "ultimately target[ ] the same fraudulent scheme." Poteet, 619 F.3d at 115. And, as the Sixth Circuit warned, courts should guard against the ability of "potential *qui tam* plaintiff's [sic] to avoid the public disclosure bar by pleading their complaints with more and more detailed factual allegations slightly different from more general allegations already publicly discussed." Dingle v. Biopart Corp., 388 F.3d 209, 215 (6th Cir. 2004). "Given that the purpose of the *qui tam* action is to prosecute fraud of which the government is unaware, such a result would not advance Congress' purpose, and would only multiply the number of parasitic *qui tam* actions pursued by plaintiffs." Id. Here, public disclosures revealed that Defendants (1) allegedly misrepresented to doctors and hospitals that the pain pumps were approved for use in joint space by the FDA and (2) failed to reveal adverse side effects to doctors or the FDA. The logical consequence of these misrepresentations (assuming the correctness of Plaintiff's depiction of the repayment programs' requirements and other legal theories) is that any doctor or hospital seeking payment from these federal programs would be submitting a false claim for payment. Thus, Plaintiff's claims are simply the logical and obvious consequence of information that was already publicly disclosed and, thus, is itself included as part of that public disclosure. Permitting Plaintiff's claim would mean that anyone could bring a qui tam action by regurgitating any pharmaceutical company's publicly known mis-, mal-, or nonfeasance and simply adding "and that publicly-known fact caused someone to submit a false claim to the government." The "essential element" of the FCA claim – Defendants' transgressions – were already publicly disclosed. Cf. United States ex rel. Hixson v. Health Mgt Sys., Inc., 613 F.3d 1186, 1188 (8th Cir. 2010); United States ex rel. Rabushka v. Crane Co., 40 F.3d 1509, 11514 (8th Cir.), cert. denied, 515 U.S. 1142 (1995); see also United

States ex rel. Springfield Terminal Ry. Co. v. Quinn, 14 F.3d 645, 654-55 (D.C. Cir. 1994) (cited with approval in Crane).

3.

Plaintiff was not the original source of the publicly disclosed information. An original source is one "who has direct and independent knowledge of the information on which the allegations are based and has voluntarily provided the information to the Government" before filing the qui tam suit. 31 U.S.C. § 3730(e)(4)(B).[9] The Eighth Circuit has held the requirements of "independent" and "direct" knowledge are distinct. "'Independent knowledge' has been consistently defined as knowledge that is not dependent on public disclosure." United States ex rel. Barth v. Ridgedale Elec., Inc., 44 F.3d 699, 703 (8th Cir. 1995). While Plaintiff suspected a connection between pain pumps and chondrolysis, he really didn't learn of this fact until he read the published studies. Therefore, Plaintiff did not have independent knowledge for the (a) subclaims. In addition, he lacked direct knowledge of the facts supporting all of his claims. To say the knowledge is "direct" means the relator obtained personal knowledge of the information on his or her own and did not derive it from other sources. "A relator has direct knowledge when he sees it with his own eyes." Stoltz, 327 F.3d at 674 (citing Barth, 44 F.3d at 703). This is because "[t]he False Claims Act is intended to encourage individuals who are either close observers or involved in the fraudulent activity to come forward, and is not intended to create windfalls for people with secondhand knowledge of the wrongdoing." Id. Therefore, a person cannot have direct and independent knowledge of information (and thus cannot be an original source) if he or she obtained the information second-hand. This is true even if that information was derived from an original source. Hays, 325 F.3d at 990-91; Barth, 44 F.3d at 703-04.[10]

[9] The PPACA added a requirement that information provided to the government must "materially add[ ] to the publicly disclosed allegations or transactions," but this additional requirement need not be discussed because of the Court's conclusion that Plaintiff does not have direct knowledge.

[10] A simpler way to insure the relator actually has direct and independent knowledge is to require that the relator either be the cause of the public disclosure or

With respect to the (a) allegations of Counts I – IV, Plaintiff did not have direct knowledge of the connection between pain pumps and chondrolysis. He responded to inquires from other doctors conducting studies, and later learned the results of those studies. Neither his suspicions of a connection nor his concerns over the lack of testing constitute knowledge – much less direct knowledge – that pain pumps caused chondrolysis. Therefore, Plaintiff is not an original source of the information giving rise to the (a) component of Counts I – IV.

Plaintiff cannot be an original source of the information giving rise to the (b) and (c) component of Counts I – IV for a more fundamental reason. Plaintiff's Declaration does not claim he told the Government Defendants misrepresented that the FDA had approved pain pumps for use in joint space, nor (for the most part) does he even profess to have such knowledge, particularly with respect to I-Flow and Breg/Orthofix. The closest Plaintiff comes to such a disclosure is described in paragraph 12 of his Declaration:

> I have independent and direct knowledge that a percentage of orthopedic surgical patients of [the hospital where Plaintiff worked] were Medicare, Medicaid or other federal insurance programs patients. Some number of pain pumps were implanted into these patients and the procedures were submitted for payment to the Federal government. There is no doubt that this same process occurred at many other hospitals and surgical centers

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disclose the information to the Government before it is publicly disclosed. See United States ex rel. Duxbury v. Ortho Biotech Prods., L. P., 579 F.3d 13, 22 (C.A.1 2009) (discussing cases). The Eighth Circuit has not expressed a view on this issue. For that matter, the Supreme Court has also declined to address whether either or both rules are the natural consequence of one having direct and independent knowledge. Schindler Elevator Corp. v. United States ex rel. Kirk, 131 S. Ct. 1885, 1895 n.8 (2011) (noting circuit split). Such a rule would make the analysis simpler, as anyone who (1) is not the source of public disclosures and (2) did not divulge information to the Government before it was publicly disclosed is not the type of person the qui tam action was designed to encourage. Such a rule would effectively insure a person who remained silent and "reported" to the Government only after the facts came to light via some other source would not be rewarded. If this rule were valid, it would easily demonstrate Plaintiff is not an original source, as he was not the source of the public disclosures and did not report his "knowledge" to the Government before the public disclosures were made. This analysis is clearly called for after the PPACA amendment. See note 8, supra. In an abundance of caution, the Court will not apply such a rule to the pre-PPACA analysis absent clear guidance from either the Eighth Circuit or the Supreme Court.

> around the country. I am also certain that had the pain pump companies disclosed to orthopedic surgeons, hospitals and surgical centers that these devices had been affirmatively rejected by the FDA for this use, responsible orthopedic surgeons would not have used them and hospitals would not have submitted such claims for payment to the Federal government.

The paragraph does not allege any Defendant misrepresented the status of FDA approval. All it says is that if Defendants had made proper representations, then Plaintiff is "certain" no doctor or hospital would have used pain pumps for this purpose. Because of his certainty, Plaintiff concludes false representations must have been made. This is speculation: Plaintiff's statement actually disclaims knowledge and reveals none of the content of Defendants' representations.

Plaintiff presents no argument suggesting why he is an original source for information that Defendants failed to file medical device reports with the FDA. The Court therefore has no basis for holding Plaintiff is an original source.

The Amended Complaint also fails to assist Plaintiff. Using the allegations involving Stryker (the Defendant with which Plaintiff is most familiar since he was once a consultant to Stryker) as an example, the Amended Complaint alleges Plaintiff saw "sales presentations and demonstrations" that caused him to understand and believe use of pain pumps in joint space was an authorized and approved use. Amended Complaint, ¶ 84; see also Amended Complaint, ¶ 86. The next paragraph alleges Stryker did not advise Plaintiff "or as far as he knows advise his colleagues" that the FDA had specifically declined to issue such approval. Amended Complaint, ¶ 85. This is significant because Plaintiff has no knowledge as to what other doctors were told, and could not have divulged any such information to the Government. Finally, the Amended Complaint confirms his lack of first-hand knowledge regarding representations about reimbursement from federal coffers. The best he can allege is that "[o]n information, Dr. Paulos believes that Stryker sales representatives provided information to orthopedic surgeons and hospitals concerning ways to bill for use of the pain pumps in orthopedic surgeries in order to obtain reimbursement for the pumps." Amended Complaint, ¶ 87. This explicitly states Plaintiff has no direct information. I-Flow similarly is alleged to have failed to disclose the FDA's rejection in its promotional literature, but Plaintiff does

not claim to have heard any representations from I-Flow. Amended Complaint, ¶¶ 138-40. Allegations involving Breg are also couched in terms of supposed omissions, but Plaintiff does not contend Breg made any representations to him or, for that matter, that he personally heard any sales promotions. Amended Complaint, ¶¶ 181-82, 186. The Amended Complaint reiterates Plaintiff's personal belief (similar to the one in his Declaration) "that had Defendants disclosed to the surgeons and hospitals that the pain pumps were not only unapproved for such use, but had been affirmatively rejected for such use by the FDA, the hospitals would not have submitted such claims to the government programs." Amended Complaint, ¶ 189. Exhibit 1 to the Amended Complaint purports to be a list of seventy-seven individuals whose orthopedic procedures were paid for by a federal benefit program, Amended Complaint, ¶ 13, but (1) there is no allegation as to what their doctors were told and (2) there is no allegation that reimbursement for the pain pump was sought or paid (as opposed to the "reimbursable" portions of the procedures in question).

Ultimately, then, Plaintiff does not allege direct knowledge of any of the claims in the Amended Complaint. At most, he alleges suspicions, strongly-held beliefs, and facts he learned second-hand from others. Plaintiff learned about the connection between pain pumps and chondrolysis from others. He does not have direct knowledge of any affirmative misrepresentations made by Defendants, and Counts I through IV are predicated on affirmative misrepresentations. He does not have any direct knowledge that any doctors or hospitals were induced by Defendants to make false claims; he only speculates that this happened. Therefore, Plaintiff cannot be an original source for any of the information giving rise to Counts I through IV.

B. Failure to State a Claim

The liberal pleading standard created by the Federal Rules of Civil Procedure requires "a short and plain statement of the claim showing that the pleader is entitled to relief." Erickson v. Pardus, 551 U.S. 89, 93 (2007) (per curiam) (quoting Fed. R. Civ. P. 8(a)(2)). "Specific facts are not necessary; the statement need only 'give the defendant fair notice of what the . . . claim is and the grounds upon which it rests.'" Id. (citing Bell

Atlantic Corp. v. Twombly, 550 U.S. 544, 555 (2007)). In ruling on a motion to dismiss, the Court "must accept as true all of the complaint's factual allegations and view them in the light most favorable to the Plaintiff[ ]." Stodghill v. Wellston School Dist., 512 F.3d 472, 476 (8th Cir. 2008).

> To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face. A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged. The plausibility standard is not akin to a probability requirement, but it asks for more than a sheer possibility that a defendant has acted unlawfully. Where a complaint pleads facts that are merely consistent with a defendant's liability, it stops short of the line between possibility and plausibility of entitlement to relief.

Ashcroft v. Iqbal, 129 S. Ct. 1937, 1949 (2009).

> In keeping with these principles a court considering a motion to dismiss can choose to begin by identifying pleadings that, because they are no more than conclusions, are not entitled to the assumption of truth. While legal conclusions can provide the framework of a complaint, they must be supported by factual allegations. When there are well-pleaded factual allegations, a court should assume their veracity and then determine whether they plausibly give rise to an entitlement to relief.

Id. at 1950.

1. Count V

Defendants sought dismissal of Count V, asserting it does not state a claim for which relief can be granted. Plaintiff acquiesces in dismissal of this count – curiously, because he concedes he lacks any personal knowledge of any false claims asserted under Count V. Plaintiff's Suggestions in Opposition at 29. Regardless of Plaintiff's reasons, the Court accepts the concession that Count V should be dismissed.

2. Count VI

Count VI is predicated on section 3729(a)(1)(B) which, prior to 2009, imposed liability on a person who "knowingly makes, uses, or causes to be made or used, a false record statement to get a false or fraudulent claim paid or approved by the Government." The Supreme Court interpreted this provision as requiring "not proof that the defendant caused a false record or statement to be presented or submitted to the Government but that the defendant made a false record statement for the purpose of getting a false or fraudulent claim paid or approved by the Government." Allison Engine Co. v. United States ex rel. Sanders, 553 U.S. 662, 671 (2008) (quotations omitted). As an example, the Supreme Court posited that when a subcontractor "makes a false statement to a private entity and does not intend the Government to rely on that false statement as a condition of payment, the statement is not made with the purpose of inducing payment of a false claim by the Government.'" Id. at 672. The essence of the holding was that the party creating the false record or statement had to have the specific intent that the Government pay the claim. This is the state of the law applicable to most of Plaintiff's claims.

Congress amended the statute in 2009 in an attempt to legislatively curtail Sanders. The statute now imposes liability when a person "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim." This change removed the requirement that the creator of the false record specifically intend the Government to pay the claim, but retained the requirement that there be a nexus between the false record and the claim submitted to the Government. E.g., United States ex rel. Wall v. Circle C Const., LLC, 697 F.3d 345, 355 n.3 (6th Cir. 2012).

Count VI alleges, at best, that Defendants failed to submit certain reports to the FDA. The parties argue over whether the failure to make a report constitutes a "false report" within the meaning of section 3729(a)(1)(B), and on that issue the Court concludes Defendants are correct – it does not. In addition, there is no connection alleged between the failure to make the report to the FDA and any false claim for payment. Finally, Plaintiff has not alleged Defendants acted with the specific intent to

induce payment from the Government when they failed to submit medical device reports to the FDA, as required by Sanders prior to the 2009 amendment.

(a)

The change in the law does not alter the requirement that Plaintiff allege and demonstrate a Defendant created a false record or statement. Plaintiff does not contend Defendants created a false record or statement; instead, Plaintiff contends Defendants failed to create and submit the required reports of adverse reactions, and the failure to create the reports equals the creation of a false statement. Plaintiff's interpretation of section 3729(a)(1)(B) is inconsistent with its clear language, which requires the defendant make, use or cause to be made or used a false record. Defendants did not make, use or cause to be made false reports to the FDA, so section 3729(a)(1)(B) cannot apply.

The *only* authority Plaintiff relies upon is a 1996 decision from the Southern District of Ohio. The paucity of authority – and the lack of any binding authority – causes the Court to hesitate. If Plaintiff's remarkably broad theory is valid, the Court would expect more to validate it than one district court decision in the last twenty-seven years. In any event, the case Plaintiff relies upon does not stand for the broad proposition Plaintiff advances. In that case, the subcontractors were tugboat operators who served as subcontractors on a project to construct and repair the Gallipolis Lock and Dam. Pickens v. Kanawha River Towing, 916 F. Supp. 702, 704-05 (S.D. Ohio 1996). The relator alleged the general contractor's contract with the Government required that all work comply with the Clean Water Act ("CWA"), and the subcontractors "made false statements by submitting their bills to [the general contractor] without acknowledging they breached the contract by violating the CWA." Id. at 705. The subcontractors argued they could not be held liable for submitting a false record because they did not affirmatively represent they had complied with the CWA. The court rejected the argument and held the submission of invoices to the general contractor constituted an implicit representation that they had complied with the CWA. Id. at 707.

The lesson of Pickens is that an omission from a record or statement can render the record or statement false or fraudulent. Pickens does not hold the total absence of a record or statement can constitute a false record. Nothing in Pickens suggests the district court would have allowed the suit to continue if the subcontractors had not submitted an invoice or other claim for payment. Here, Plaintiff identifies no record or statement submitted by Defendants to hospitals or doctors that was rendered false or fraudulent by an omission from that record or statement. Accordingly, Pickens – assuming it is a correct statement of law – does not apply to this case.

(b)

The second flaw in Count VI is the absence of any allegation connecting (1) Defendants' failure to make reports to the FDA to (2) a claim for payment submitted to the Government. For purpose of this discussion, the Court will presume the absence of a record can constitute a false or fraudulent record for purposes of section 3729(a)(1)(B). Prior to 2009, Defendants could be liable only if they failed to create the FDA report in order "to get a false or fraudulent claim paid or approved by the Government." 31 U.S.C. § 3729(a)(2) (the predecessor to current section 3729(a)(1)(B)). Plaintiff has alleged no facts connecting the absent report to the FDA to any doctor's or hospital's claims for payment. After the 2009 amendment, Plaintiff would have to plead and demonstrate the absent report was "material" to a doctor's or hospital's claim for payment. Again, nothing demonstrates the materiality of the reports. Count VI does not allege any connection between the false/omitted FDA reports and the claims submitted by doctors and hospitals. See 31 U.S.C. § 3729(c) (pre-2010 definition of "claim"); 31 U.S.C. § 3729(b)(2) (current definition of "claim").

The FCA provision Plaintiff invokes is designed to impose liability on those who submit false records to another party who uses those records to support a claim for payment from the Government. Plaintiff's theory is that the absent report should have been given to the FDA – it would not have been given to a doctor or hospital and would not have been part of any doctor's or hospital's claim for payment, as those terms are statutorily defined.

In addition, Plaintiff's theory strays too far from the FCA's purpose. Crediting Plaintiff's theory would impose FCA liability anytime a drug/device manufacturer fails to comply with an FDA requirement. For that matter, Plaintiff's theory would impose liability under the FCA every time a drug or device manufacturer is alleged to have negligently tested a drug or device because in every such instance the manufacturer can be alleged to have failed to reveal the absence of health benefits. There are remedies for such failures under the FDA's regulatory scheme or tort law, but the FCA is not one of those remedies.[11]

(c)

Per the Supreme Court's decision in Pickens, prior to Congress' amendment in 2009 Defendants could be liable only if they had the specific intent of causing the Government to file a false claim when they failed to submit the medical device reports to the FDA. Plaintiff simply has not made any such allegation. Thus, Count VI must be dismissed for failure to state a claim to the extent it is based on violations before the statute was amended.

3. Counts I – IV

The Court rejects Defendants' arguments that Counts I – IV fail to state a claim because they are too fact-bound for proper consideration under Rule 12(b)(6). While repayment under the Government programs are governed by various regulations, the parties' description of how those regulations work persuades the Court the issue is not a purely legal matter. This makes it impossible to credit either parties' descriptions about the repayment programs, how they operate, the billing procedures employed, or the materiality of any of the allegations in Counts I – IV. Full consideration of these matters

[11]The Court also notes the Amended Complaint alleges Breg filed thirteen reports related to Breg's pain pump with the FDA between 1999 and 2009. Amended Complaint, ¶ 176. Plaintiff's claim is based on the absence of reports, not the inadequacy of the number of reports, so this allegation seems to eviscerate the claim against Orthofix for any of Breg's misconduct.

requires examination of factual materials that are not contained in the Amended Complaint. The issues raised are best dealt with on summary judgment (assuming the decision to dismiss Counts I – IV based on the Public Disclosure Bar is reversed).

4. Orthofix

Orthofix is not alleged to have engaged in any of the wrongful acts described in the Amended Complaint. Breg is alleged to have engaged in wrongful acts; Orthofix is sued simply because it bought Breg and Plaintiff concludes Orthofix "is the successor in interest to Breg . . . ." Amended Complaint, ¶ 8. Plaintiff's allegation that Orthofix is Breg's successor in interest is a legal conclusion that Iqbal and Twombley dictate is not entitled to a presumption of correctness. Plaintiff must allege facts that make Orthofix liable for Breg's wrongdoing, and Plaintiff has not done so.

Orthofix has submitted public documents to prove the circumstances of its purchase of Breg. Plaintiff counters that consideration of such materials is improper under Rule 12(b)(6), which is probably not true. But see page 7, supra. In an abundance of caution the Court has elected not to consider the documents Orthofix submitted – but Plaintiff's claims must still be dismissed because the Amended Complaint remains devoid of any factual basis for imposing liability on Orthofix.

Plaintiff seeks an opportunity to conduct discovery so it can ascertain "whether and to what extent Orthofix, as the corporate parent, played a role in the pain pump marketing process" and promises that "[i]f Orthofix can demonstrate, after discovery, that it had no r[o]le, summary judgment in its favor may be proper. However, whether [Orthofix[is a proper party is a matter of an affirmative defense upon which Orthofix bears the burden of proof." Plantiff's Suggestions in Opposition to Orthofix (Doc. # 75) at 2. Plaintiff has placed the cart before the horse. Before discovery is justified, Plaintiff must first allege – consistent with the dictates of Iqbal and Twombley – that Orthofix is liable. Plaintiff's obligation includes a requirement that it allege how Orthofix is liable for Breg's conduct: this is *not* an affirmative defense (and the case Plaintiff cites does not mention this issue). Plaintiff has failed in this initial step, so the claims against Orthofix must be dismissed for failure to state a claim.

C. Statute of Limitations

The FCA's statute of limitations is six years from the date of violation, 31 U.S.C. § 3731(b)(1), and Defendants argue Plaintiff's claims are time-barred to the extent they assert claims for conduct before January 10, 2005. Plaintiff argues that 18 U.S.C. § 3287 (referred to as "the Suspension Act") tolls the statute of limitations. This statute provides that "[w]hen the United States is at war or Congress has enacted a specific authorization for the use of the Armed Forces, as described in section 5(b) of the War Powers Resolution, the running of any statute of limitations applicable to any offence (1) involving fraud or attempted fraud against the United States . . . shall be suspended" until five years after the hostilities are ended. Plaintiff contends this tolling provision applies because Congress authorized the President to use military force in Afghanistan in September 2001 and United States troops are still in that country. The Court agrees that the Suspension Act applies.

Defendants' arguments against applying the Suspension Act are unpersuasive. They first contend it applies only to criminal cases, but the weight of authority is to the contrary. See United States ex rel. Carter v. Halliburton Co., 710 F.3d 171, 179-80 (4th Cir. 2013) (citing cases). As the Fourth Circuit explained, at one time the Suspension Act applied to "indictable offenses" but was amended in 1944 to apply to "offenses." This change has been interpreted as broadening the Suspension Act's scope to embrace civil as well as criminal fraud. Defendants' second argument is that the only "fraud" the Suspension Act applies to are "war frauds" – that is, frauds related to the administration of the war. This argument asks the Court to add language to the statute that does not exist. Defendants cite cases applying the Suspension Act to war frauds, but they do not cite any – much less any that bind this Court – holding that the Suspension Act applies *only* to war frauds.[12]

[12]The Court's decision makes it unnecessary to consider whether either Count II or Count III qualify as a "war fraud."

D. Rule 9(b)

The parties agree Plaintiff's claims must satisfy the heightened pleading requirements of Rule 9(b). Cf. United States ex rel. Joshi v. St. Luke's Hosp., Inc., 441 F.3d 552, 556-57 (8th Cir. 2006); Stoltz, 327 F.3d at 674-75. This requires Plaintiff to identify the "who, what, where, when, and why" of the fraud. The Court concludes Plaintiff has satisfied this requirement.

III. CONCLUSION

The Court has reached the following conclusions, some of which overlap and result in dismissal of certain counts or parties on multiple grounds.

1. Defendants' request to bar or limit Plaintiff's claims based on the statute of limitations is denied.

2. Defendants' request to dismiss the case based on Plaintiff's failure to satisfy Rule 9(b)'s requirements is denied.

2. Count V is dismissed based on Plaintiff's concession that the claim should be dismissed.

3. Defendants' request to dismiss the Amended Complaint based on the Public Disclosure Bar is granted with respect to Counts I – IV and Count VI. In light of Plaintiff's concession, no decision is made with respect the Public Disclosure Bar's applicability to Count V.

4. Defendants' request to dismiss the Amended Complaint for failure to state a claim is granted with respect to Count VI but denied as to Counts I – IV without prejudice to Defendants re-asserting those arguments in a summary judgment motion.

5. All claims against Orthofix are dismissed for failure to state a claim.

IT IS SO ORDERED.

/s/ Ortrie D. Smith
ORTRIE D. SMITH, SENIOR JUDGE
UNITED STATES DISTRICT COURT

DATE: June 12, 2013